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Original Research

Treatment outcomes among smear positive tuberculosis patients in Dire Dawa Administration, East Ethiopia

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Abstract

Introduction: Tuberculosis is one of the leading causes of death from infectious disease worldwide, and it kills around 1.5 million people in a year. This study was identified treatment outcome of smear positive pulmonary tuberculosis and its associated factors.

Method: A retrospective medical record review of 1233 spear positive pulmonary tuberculosis patients registered from July 01/ 2010 to June 30/2013 in randomly selected six public health facilities were undertaken. Univariate, bivariate analysis, chi- square test and multivariable logistic analysis was conducted with consideration of P value < 0.05 with 95% CI.

Results: 1022 (83.0%) end with favorable treatment outcome, while 270 (17.0%) ends with unfavorable treatment outcome. In multivariable logistic regression, the patients who had no treatment supporter or contact person AOR=2.21 with 95% CI (1.58, 3.26), being treatment failure category were AOR=6.35 with 95% CI (2.51, 16.14) and sputum smear positive at end of 5th months were AOR=16.7 with 95% CI (11.21, 23.42).

Conclusion: the following factors were identified as determinants of unfavorable treatment outcome: having no treatment supporter, treatment failure category and smear positive at end of 5thmonth. The tuberculosis patients should be supported during treatment and restrict monitoring and evaluation of patients during Directly Observed Treatment Short course (DOTS) were required.

Key words: Treatment outcomes, Smear positive tuberculosis, Unfavorable outcome

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1. Introduction

Regardless of accessibility and availability of effective treatment for long time, tuberculosis (TB) remains a major global health problem. In 2014, worldwide, 9.6 million people were estimated to have TB and 1.5 million deaths [1]. Global efforts to control tuberculosis (TB) were strengthened in 1991, when a World Health Assembly resolution recognized TB as a major global public health problem and then in 1994, WHO established directly observed treatment-short course (DOTS) strategy. Global Plan (2011–2015) updated DOTS in detail in the way that to achieve a case detection rate (CDR) of 84% (for all cases and smear-positive cases specifically) and a treatment success rate (TSR) of 87% by 2015[2]. In all, effective diagnosis and treatment of TB saved an estimated 43 million lives between 2000 and 2014. The MDG target to halt and reverse TB incidence has been achieved on a worldwide basis, in each of the six WHO regions and in 16 of the 22 high-burden countries that collectively account for 80% of TB cases [1].

Ethiopia is among the High TB Burden Countries (HBCs), that accounted for 80% of all estimated TB cases worldwide, with annual estimated TB incidence of 207/100,000 populations (i.e., 200,790) and death rate of 33 per 100,000 populations (i.e., 32,010 deaths) [3]. Ethiopia adopted the DOTS strategy since 1997 after successful pilot program with the development of the first combined tuberculosis and leprosy prevention and control program manual. TB/HIV collaborative activities were piloted in 2004 and subsequently scaled up nationally [3].

Investigating the status of DOTS to monitor the TB program is essential. For this reason, the studies undertaken in some part of our country, Ethiopia to see treatment outcome. In so far study done in south Ethiopia shows that distance from home to treatment center, age > 25 year and necessity to use public transport to get to a treatment center found to be independently associated with defaulting from treatment that affect the favorable treatment outcome [4]. In addition, different study under taken in the country documented independent risk factors for poor treatment outcome. These factors are attending the regional capital health center, being on retreatment, having a positive smear at the second month follow-up, age being greater than 55 years, being male, medication side effects, low body weight at initiation of anti-TB treatment (<35 kg), year of enrollment, distance from home to treatment center and the added burden of using public transport to get to a treatment center [4-7].

The Dire Dawa Administration has an estimated population of 396, 423 and 100% DOTS geographical coverage. The DOTS program has been introduced in hospital, health centers and in most health posts in the administrative region [8].

2. Methods

2.1. Study setting

Study was done at Dire Dawa Administration, eastern Ethiopia and in study, six public health facilities included that was three urban health centers, one hospital and two rural health centers where DOTS program implemented fully. According to 2007 Ethiopian census projection for 2013/14, the current total population of Dire Dawa Administration is 396, 423 (58% residing in urban). Dire Dawa Administration has 9 urban and 38 rural Kebeles [9].

2.2. Study design and data collection

A retrospective analysis of the profile and treatment outcome smear positive pulmonary TB in Dire Dawa Administration detected, registered and treated from July 01/ 2010 to June 30/2013. The check list was developed to collect the data from the TB registration documents were reviewed that contains basic information such as patient's age, sex, address, tuberculosis type, and treatment outcomes.

Data were collected by trained nurses. Preference was given to recruit nurses those who took basic training of TBL and TB/HIV. Interviewers were recruited from institutions working under Dire Dawa Administration Health Bureau staffs based on the criteria set for the recruitment of the data collectors. Bachelor degree graduate with nursing who had experience in the supervision were recruited to serve as supervisors.

2.3.Sample size and sampling technique

In this study, sample size was calculated by considering the proportion of smear positive PTB patients with unsuccessful treatment outcome as a predictor variable. Sample size is determined using single population proportion formula. The following parameters were taken into account during calculation of sample size: based on study done at North Ethiopia, Tigray Region [7] shown that proportion of unfavorable outcome (P) among smear positive TB patients were 10.8%, 95% confidence interval (Z) and a maximum discrepancy of (d) 3% between the sample and the underlying population; then the result was multiplied by 3 to consider the health facilities cluster effect and increase power. Thus, 1233 study participants' data were included. Health facilities sampling was performed through selecting two out of seven rural health

centers; three out of nine from urban health centers and one hospital out of two were randomly selected and finally, incomplete data of smear positive pulmonary TB were excluded.

2.4.Data analysis

The data were coded and entered into the data sheet using EPI version 6.0 statistical packages and cleaned and then exported to SPSS version 16.0 for further analysis. All continuous variables were described using mean and standard deviation whereas for categorical data as frequency (%). Treatment success rate (TSR), treatment cure rate and proportion of respective unfavorable treatment outcome were calculated as the percentage of those who were categorized as favorable treatment outcome and all study respondents as the denominator. The frequency distribution of dependent and independent variables worked out in 95% CI. Chi square, bivariate analysis and multivariable logistic regression were applied to determine predictor variables on the outcome variables.

2.5.Treatment outcomes definition

Favorable outcome: if pulmonary TB smear positive patients were cured (i.e., negative smear microscopy at the end of treatment and on at least one previous follow-up test) or completed treatment with resolution of symptoms.

Unfavorable outcome: if treatment of pulmonary TB smear positive patients resulted in treatment failure (i.e., remaining smear positive at 5 or after 5 months of treatment), default (i.e., patients who treated for a month or more and who interrupted their treatment for consecutive two months or more after registration), or death (from any cause), and transferred out (patients who transferred to other health facility

3. Results

3.1.Socio demographic and clinical characteristic

The data of smear positive TB patients collected from TB register for 1232 patients for the period of four years (2010-2013) attending health facilities in Dire Dawa Administration. Of these, 735(59.7%) were males with the mean age of 31.0 $\pm$12.6 years. Ninety eight percent (n = 1207) of the patients were urban resident. (Table 1).

Among 1232 smear positive TB patients 82.5% had treatment supporter during their treatment follow up and the majority of them 78.2% were new smear positive TB patients. (Table 2).

Table1. Socio demographic characteristics of smear positive TB patients from 2010-2013 at Dire Dawa, Ethiopia

Variables	Number	Percent
Type of health facility		
Health center	1050	85.2
Hospital	182	14.8
Data year		
2010	172	14.0
2011	488	39.6
2012	270	21.9
2013	302	24.5
Residence		
Urban	1207	98
Rural	25	2
Has no house number/new	2	2
Age		
<=14 year	29	2.4
15-24year	398	32.3
25-34 year	399	32.4
35-44year	197	16
45-54year	125	10.1
55-64 year	64	5.2
>=65 year	20	1.6
Sex		
Male	735	59.7
Female	497	40.3

At study site, Dire Dawa, the provision of anti -TB drug for patients of category I treatment were 82.6 % and sputum smear microscopic follow up done for 1072 patients at end of 2 or 5 month follow up. Of them 86.2% were found negative. (Table 2)

We also assessed the TB /HIV services and prevalence of co-infection. Of the total smear positive TB patients data included for study, HIV test offered for 99.1% and test was performed nearly for all 98.9%. From those who had recorded data for HIV test, the prevalence of TB/HIV co-infection was 17.3 %.(Table 2)

Table 2. Clinical characteristics of smear positive TB patients from 2010-2013 at Dire Dawa, Ethiopia

Smear positive pulmonary TB treatment outcome and associated factors

Variables	Number	Percent
Has the patient contact person/treatment supporter?	N=1232	
Yes	1016	82.5
No	216	17.5
Patient category		
New (N)	972	78.2
Relapse (R)	177	14.4
Return after default (D)	25	2
Treatment failure (F)	19	1.5
Transfer in (T)	39	3.2
Others (O)		
Category of the treatment		
Category I	1018	82.6
Category II	214	17.4
Follow up Sputum Smear result at end of 2nd /3rd months	N=1167	
Positive	84	7.2
Negative	988	86.2
Not done	118	10.3
Follow up sputum smear result at end of 5th months	N=1143	
Positive	37	3.2
Negative	988	86.4
Not done	118	10.3
Follow up sputum smear result at end of 6th /8th months	N=1139	
Positive	10	0.9
Negative	812	71.3
Not done	317	27.8
HIV test offered	N=1221	
Yes	1211	99.1
No	20	0.01
Was HIV test performed	N=1215	
Yes	1202	98.9
No	13	1.1
HIV/AIDs Status of the patient	N=1207	
Reactive	209	17.3
Non-reactive	994	82.4
Not done	3	0.2
Unknown	1	0.1

We analyzed treatment outcome of 1232 smear positive tuberculosis patients who were registered at health facilities during the study period. Of these, 1022 (83%) end with favorable treatment outcome, while 210 (17.0%) end with unfavorable treatment outcome that were 40 (3.2%) defaulted, 84 (3.9%) died, 36 (2.9%) treatment failure and 86 (7.0%) transferred out to other health facilities and the overall cure rate was 62.2%. After we under taken chi- squared test some variables were associated with treatment outcomes (Table 3).

Table 3. Treatment outcomes of smear positive TB by age, sex, HIV status, pateints who had contact person, pateints category and treatmnt catagory from 2010 to 2013 in Dire Dawa, Ethiopia

	Patient treatment outcomes								
	Cure	Treatment completed	Failed	Defaulted	Died	Transferred out	Total	X2	P-value
Sex								2.2	0.81
Male	459	155	22	25	24	50	735		
Female	307	101	14	15	24	36	497		
Total	766	256	36	40	48	86	1232		
HIV /AIDS status of patients								35.2	<0.0001
Reactive	135	36	3	11	18	6	209		
Non-reactive	619	212	33	28	25	78	995		
Not done	5	4	0	0	1	0	10		
Total	759	252	36	39	44	84	1214		
Patient has contact person								25.7	<0.0001
Yes	650	217	28	30	33	58	1016		
No	116	39	8	10	15	28	216		
Total	766	256	36	40	48	86	1232		
Patient category								52.5	<0.0001
New (N)	617	210	23	27	28	67	972		
Relapse (R)	100	34	8	6	17	12	177		
Treatment Failure(F)	8	1	3	2	2	3	19		
Transfer in (T)	27	7	1	3	0	1	39		
Return after defaulter (D)	14	4	1	2	1	3	25		
Total	766	256	36	40	48	86	1232		
Treatment category									
Category I	640	217	24	30	28	68	1007	52.5	<0.0001
Category II	126	39	12	10	20	18	225		
Total	766	256	36	40	48	86	1232		

3.2.Determinants of unfavorable treatment outcome for smear positive pulmonary TB

In multivariable logistic regression, three variables were remain in the model that was the patients who had no treatment supporter or contact person were 2.21 times more likely to end up with unfavorable treatment outcome, AOR=2.21 with 95% CI (1.58, 3.26) when compared with those who had treatment supporter and being treatment failure category were 6.35 times more likely end up with unfavorable treatment outcome, AOR=6.35 with 95% CI (2.5, 16.14) when compared with new treatment category and those who had sputum smear positive at end

of 5th months were 16.7 times more likely to end up with unfavorable treatment outcome, AOR =16.7 with 95% CI (11.21, 23.42) when compared with smear negative patients at end of treatment (Table 4).

Table 4. Determinants of favorable treatment outcome for smear positive pulmonary TB from multivariable logistic regression model in Dire Dawa, Ethiopia

VARIABLE	Treatment out comes		COR at 95%CI	AOR at 95%CI
	Favorable	Unfavorable		
Patient has contact person				
Yes	867	149	1	1
No	155	61	2.29 (1.6,3.2)	2.21 (1.58,3.26)
Patient category				
New (N)	827	145	1	1
Relapse (R)	134	43	1.83 (1.24,2.6)	1.9 (1.31,2.87)
Transfer in (T)	34	5	1.23 (1.12,2.18)	2.27 (1.58,3.25)
Return after defaulter (D)	18	7	2.21 (0.91,5.4)	2.39 (0.96,5.95)
Treatment failure (F)	9	10	6.33 (2.5,15.8)	6.35 (2.51,16.14)
Sputum examination result at 2nd month				
Negative	945	97	1	1
Positive or not done	77	113	14.3 (10.0,20.4)	12.1 (8.72,19.32)
Sputum examination result at 5th month				
Negative	958	15	1	1
Positive or not done	63	107	18.5 (9.7,22.7.2)	16.7 (11.21,23.42)

4. Discussion

Assessment of treatment outcomes and analysis of factors responsible for unfavorable treatment outcome in DOTS program is important particularly in smear-positive PTB patients as they transmit a contagious form of M. tuberculosis.

In this study, favorable treatment outcome in smear-positive PTB patients was 83%, slightly lower than the WHO international target 87% [2], Tigray 89.2% [7] and a study conducted in Southeast Nigeria 88.7% [10] but higher than previous studies conducted in some parts of Ethiopia which was 77% in Southern region [4], and 29.5% in Gondar area of Ethiopia [5].

Our finding comparatively higher favorable treatment outcome in Dire Dawa Administration as compared to other areas in Ethiopia might be the result of 100% DOTS geographical coverage. The DOTS program has been introduced in hospital, health centers and in most health posts in the administrative according to Dire Dawa Administrative Health Bureau [8].

The unfavorable treatment outcome 17% found in our study is comparatively higher than 10.8% the finding from Tigray region [7] but lower than a study conducted in Southern region which was 26.2% [4].

The patient default 3.2% in our study was lower than study from southern region 20% [4] and Gondar, northwest, Ethiopia 18.3%, Ibadan Nigeria which was 6.6% and in China was 12.4% [5,11-12].

The death recorded in our study 3.9% was higher when compared with study done in southern region of Ethiopia 2.2%, China 3% and Ibadan Nigeria 1.9% [4,11-12] but lower when compared with the corresponding outcome from Gondar area, northwest Ethiopia, where 10.1% was died and in Addis Ababa 3.7 % patients died [6], in Finland 17.2% were died [13].

The failure rate in our study was 2.9% which was higher than study from Gondar 0.2 % [5] China 1.4% [12] but lower than a study done in Ibadan Nigeria that was 8.1%, Tigray 3.7% and Northern Nigeria 12.6 [7,11,14].

Concerning transfer out in our study 7% which was higher than a study done in Ibadan Nigeria 4.8%, in Tigray 1.47% and China 0.8% [7,11,12] but lower than study done in Gondar 42% [5].

In our study socio demographic variables like age, sex and resident, HIV status did not show statistically significant association with unfavorable treatment outcome which was consistent with the study done in Tigray, North Ethiopia [7] but age greater than 25 years old and being male in study done at Gondar and Addis Ababa [5, 6] and also age, HIV status associated with unfavorable outcome in a study done at Malaysia [15].

The factors associated with unfavorable treatment outcome in our study were the patients who had no treatment supporter or contact person were 2.21 times more likely to end up with unfavorable treatment outcome, AOR=2.21 with 95% CI (1.58, 3.26) when compared with those who had treatment supporter which is consistence with a study done in China and India [12, 16].

Our study revealed that being treatment failure category was 6.35 times more likely end up with unfavorable treatment outcome, AOR=6.35 with 95% CI (2.5, 16.14) when compared with new treatment category which is in line with a study done at Tigray, North Ethiopia as retreatment category end up with a poor treatment outcome [7]. Those who have sputum smear positive at end of 5th months were 16.7 times more likely to end up with unfavorable treatment

outcome, AOR =16.7 with 95% CI (11.21, 23.42) when compared with smear negative patients at end of treatment which is in line with a study conducted at Iran [17].

There was some limitation as we utilized secondary done that prepared for tuberculosis surveillance we committed incomplete data during data collection but we developed criteria to exclude like if there were no treatment outcome recorded for particular patients. The patient might registered or misclassified during registration. Despite this limitation the study included high sample size from health centers randomly selected from rural and urban and referral hospital, which reflect DOTS program at urban and rural of Dire Dawa Administration.

5. Conclusion

The proportion of treatment outcome as: 1022 (83%) end with favorable treatment outcome, while 210(17.0%) ends with unfavorable treatment outcome that were 40 (3.2%) defaulted, 84 (3.9%) died, 36(2.9%) treatment failure and 86 (7.0%) transferred out to other health facilities and the overall cure rate was 62.2%.

The following factors were identified as determinants of unfavorable treatment outcome: having no treatment supporter, treatment failure category and smear positive at end of 5th month. The tuberculosis patients should be supported during treatment and strong monitoring and evaluation of patients during DOTS through sputum examination should be implemented

Declaration

Ethical approval

Ethical approval for this study was waved by Dire Dawa University Ethical Review Committee, because the data was collected from secondary data sources in which difficult to obtain the consent.

Informed consent

Informed consent was not sought for the present study because the data were collected from the secondary data sources, tuberculosis registers

Competing interests

The authors declare that there is no conflict of interests.

Authors' contribution

HM: participated in all phases of preparation starting from inception of the project, collection of data, analysis and interpretation of results and writing and revising the manuscript. TM, BM, AU, KA: contributed on data collection and analysis of data. BT, YT participated in analysis, manuscript preparation, critically reviewing of the manuscript. All authors read and approved the final manuscript.

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